



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA-2016-F-3880]

Novus International, Inc.; Filing of Food Additive Petition (Animal Use); Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening the comment period for the notice of petition, published in the Federal Register of November 8, 2016 (81 FR 78528), proposing that the food additive regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food. FDA is reopening the comment period to allow additional time for comments on environmental impacts.

DATES: Submit either electronic or written comments by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

#### Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-F-3880 for "Food Additives Permitted in Feed and Drinking Water of Animals; 2-Vinylpyridine-Co-Styrene." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Carissa Doody, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240-402-6283, [carissa.doody@fda.hhs.gov](mailto:carissa.doody@fda.hhs.gov).

SUPPLEMENTARY INFORMATION: In the Federal Register of November 8, 2016 (81 FR 78528), Novus Inc. proposed regulations be amended to provide for the safe use of poly (2-vinylpyridine-co-styrene) as a nutrient protectant for methionine hydroxy analog in animal food for beef cattle, dairy cattle, and replacement dairy heifers. Additionally, the petition proposes that the food additive regulations be amended to provide for the safe use of ethyl cellulose as a binder for methionine hydroxy analog to be incorporated into animal food.

Interested persons were originally given until December 8, 2016, to comment on the petitioner's environmental assessment. The November 8, 2016, notice of petition was published with the incorrect docket number. A correction published in the Federal Register of November 29, 2016 (81 FR 85972). On our own initiative, we are reopening the comment period to allow potential respondents to thoroughly evaluate and address pertinent environmental issues.

Dated: December 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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